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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,834	04/14/2004	Ian Popoff	23546-07873 (HTS-0130US)	7795

27180 7590 10/03/2006

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,834	POPOFF ET AL.	
	Examiner	Art Unit	
	J. D. Schultz, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, and 22, drawn to nucleobase compounds targeted to SOCS-3, and to modifications thereof, classified in class 536, subclass 24.5.

II. Claims 18, 23, and 24, drawn to methods of inhibiting the expression of SOCS-3, and to methods of treating an animal, comprising the use of nucleobase compounds targeted to SOCS-3, classified in class 514, subclass 44.

III. Claims 19 and 20, drawn to methods of screening candidate antisense compounds for inhibitors of SOCS-3, classified in class 435, subclass 6. Election of this Group requires an election of species of a single nucleotide therapeutic selected from the group consisting of an oligonucleotide, an antisense oligonucleotide, a DNA oligonucleotide, and RNA oligonucleotide, a duplexed oligonucleotide, or a chimeric oligonucleotide for reasons provided below.

IV. Claim 21, drawn to a method of identifying a disease state comprising identifying the presence of SOCS-3 in a sample using any of SEQ ID NOS: 5-7, classified in class 435, subclass 6. Election of this Group requires the further election of single sequence selected from the group consisting SEQ ID NOS: 5-7, for reasons provided below.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is related to the invention of group II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product antisense oligos can be used as probes for identifying the presence of specific mRNA transcripts in *in situ* hybridization assays, which does not involve administering antisense oligos to cells, tissues, or whole animals as present in group II. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II because the searches are divergent and not co-extensive, and because a search of all inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions I and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antisense oligos of Group I are not used in a method of screening for oligos that inhibit the intended target of Group III, because the method of screening uses only candidate antisense compounds with an unknown inhibitory profile, while the oligos of Group I are known inhibitors that have had such activity characterized, and are thus specifically not useful in the method of screening for antisense inhibitors. Because the search for methods of screening for inhibitors is divergent and non-coextensive with a the search for known antisense inhibitors, and because a search of these inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions I and IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the invention of group I is drawn to compounds that inhibit SOCS-3, where is the invention of group IV is drawn to methods of detection which do not utilize the compounds of group I. Accordingly, the compounds of Group I are not used in the method of Group IV. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group IV because the searches are divergent and not co-extensive, and because a search of all inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the methods of inhibiting SOCS-3 in cells and tissues of Group II is not disclosed as useful with the method of screening for antisense inhibitors of SOCS-3, and because they use different molecules and thus have different modes of operation. For example, the method of screening for antisense inhibitors of SOCS-3 requires testing a large number of potential antisense inhibitors, which is not a step required in the method of inhibiting the expression of SOCS-3 in cells or tissues, which requires the use of known inhibitors of SOCS-3. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show

them to be obvious variants. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III because the searches are divergent and not co-extensive, and because a search of all inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Inventions II and IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the practice of the method of Group II requires the administration of a nucleobase compound, which initiates the cleavage of the mRNA target by steric hindrance or by recruiting RNase H, which does not involve combining with any of SEQ ID NOS: 5-7 and detecting the combination as required in group IV. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group IV because the searches are divergent and not co-extensive, and because a search of all inventions in a single application presents a serious burden to the examiner to search and examine in the same application, restriction for examination purposes as indicated is proper.

Inventions III and IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the method of combining SOCS-3 with any of SEQ ID NOS: 5-7 and detecting the combination of

Group IV is not disclosed as useful with the method of screening for antisense inhibitors of SOCS-3 of Group III, because they use different molecules and thus have different modes of operation. For example, the method of screening for antisense inhibitors of SOCS-3 requires testing a large number of candidate antisense inhibitors, which is not a step required in the method of combining SOCS-3 with any of SEQ ID NOS: 5-7 and detecting the combination. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV because the searches are divergent and not co-extensive, and because a search of all inventions in a single application presents a serious burden on the examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Sequences

Furthermore, should applicants elect to prosecute Group IV, the multiple sequences listed within these Groups are subject to further restriction as follows. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in Group IV are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application (see MPEP 803.04 and 2434).

Group IV specifically claims the use of SEQ ID NOS: 5-7. Each sequence is considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, each of which requires a separate search unrelated to any search for a different sequence. Furthermore, a search of more than one (1) of the sequences claimed in the Groups above presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, should applicants elect Group IV, applicants are required to elect a single sequence recited therein.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention: an oligonucleotide, an antisense oligonucleotide, a DNA oligonucleotide, and RNA oligonucleotide, a duplexed oligonucleotide, or a chimeric oligonucleotide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 19 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Ochiai

Finally, applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments

> submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. D. Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDS

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER